- 4.1 Understanding the organization and its context
- 4.2 Understanding the needs and expectations of interested parties
- 4.3 Determining the scope of the quality management system
- 4.4 Quality management system and its processes

4. CONTEXT OF THE ORGANIZATION

Internal and external environment of the organization

4.1 Understanding the organization and its context

- determine external and internal issues that are
  - relevant to its purpose and
  - its strategic direction and
  - that affect its ability to achieve the intended result

- monitor and review information about these external and internal issues.

definition

CONTEXT OF THE ORGANIZATION

combination of internal and external issues that can have an effect on an *organization's* approach to developing and achieving its *objectives*

4.1 Understanding the organization and its context

- determine external and internal issues that are
  - relevant to its purpose and
  - its strategic direction and
  - that affect its ability to achieve the intended result

- monitor and review information about these external and internal issues.

4.2 Understanding the needs and expectations of interested parties

Due to their effect or potential effect on the organization ,the organization shall determine:

- a) the interested parties
- b) the requirements of these interested parties

The organization shall monitor and review information about these interested parties and their relevant requirements.

definition

INTERESTED PARTY / stackholder

person or organization that can affect, be affected by, or perceive itself to be affected by a decision or activity

4.2 Understanding the needs and expectations of interested parties

Due to their effect or potential effect on the organization ,the organization shall determine:

- a) the interested parties
- b) the requirements of these interested parties

The organization shall monitor and review information about these interested parties and their relevant requirements.

4.3 Determining the scope of the quality management system

determine the boundaries and applicability of the QMS to establish its scope.

consider:

a) the external and internal issues
b) the requirements of relevant interested parties
c) the products and services of the organization.

apply all the requirements if they are applicable within scope of its QMS.

4.3 Determining the scope of the quality management system

The scope of the QMS shall be available and be maintained as documented information.

- types of products and services covered,
- Provide justification for any requirement not applicable to the scope of its QMS

definition

DOCUMENTED INFORMATION

information required to be controlled and maintained by an organization and the medium on which it is contained

4.3 Determining the scope of the quality management system

Conformity to this International Standard may only be claimed if

the requirements determined as not being applicable do not affect the

- organization’s ability or responsibility to ensure the conformity of its products and services and

- the enhancement of customer satisfaction.

4.4 Quality management system and its processes

4.4.1

The organization shall establish, implement, maintain and continually improve a quality management system, including:

- the processes needed
- and their interactions, in accordance with the requirements of this standard.

4.4 Quality management system and its processes

determine the processes needed for the QMS and their application throughout the organization, and determine:

- a) inputs required and the outputs expected
- b) sequence and interaction of these processes;
- c) criteria and methods
- d) resources

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4.4 Quality management system and its processes

determine the processes needed for the QMS and their application throughout the organization, and determine:

- e) responsibilities and authorities
- f) address the risks and opportunities
- g) evaluate these processes and implement any changes needed
- h) improve the processes and the QMS

4.4 Quality management system and its processes

4.4.2

To the extent necessary:

- a) maintain documented information to support the operation of its processes
- b) retain documented information to have confidence that the processes are being carried out as planned.